UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY Plaintiff, v. TEVA PARENTERAL MEDICINES, INC., APP PHARMACEUTICALS, LLC, PLIVA HRVATSKA D.O.O., TEVA PHARMACEUTICALS USA, INC., and BARR LABORATORIES, INC., Defendants.	)	Case No. 1:10-CV-1376-TWP-DKL

LETTER OF REQUEST FOR INTERNATIONAL JUDICIAL ASSISTANCE PURSUANT TO THE HAGUE CONVENTION ON THE TAKING OF EVIDENCE ABROAD IN CIVIL OR COMMERCIAL MATTERS TO THE APPROPRIATE JUDICIAL AUTHORITY IN THE UNITED KINGDOM

The United States District Court for the Southern District of Indiana ("the District Court") presents its compliments to the Senior Master of the Supreme Court of Judicature, Queen's Bench Division, and has the honor of requesting international judicial assistance in obtaining evidence to be used in civil proceedings before this Court in the above-captioned matter.

The District Court requests that the Senior Master approve the Defendants' nomination of a practicing Barrister, or such other qualified person as the Court deems fit, to act as Examiner for the purpose of obtaining oral testimony and documents for trial from a non-party witness, Dr. A. Hilary Calvert ("Dr. Calvert").

This request is made pursuant to, and in conformity with, Chapter I of the *18 March 1970 Hague Convention on the Taking of Evidence Abroad in Civil or Commercial Matters* ("the Hague Convention"), to which both the United States and the United Kingdom are a party, and Rules 28 and 30 of the United States Federal Rules of Civil Procedure.

Defendants in this matter represent that the documents and testimony sought are directly relevant to the issues in dispute, are necessary for purposes of trial, and are not discovery within the meaning of Article 23 of the Hague Convention. Defendants further represent that this Request complies with reservations made by the United Kingdom under the Hague Convention.

The particulars of this Hague Evidence Request are as follows:

1. Sender:

The Honorable Denise K. LaRue
United States Magistrate Judge
United States District Court for the Southern District of Indiana
Birch Bayh Federal Building and United States Courthouse
46 East Ohio Street, Room 105
Indianapolis, IN 46204
United States of America
Case No. 1:10-CV-1376-TWP-DKL

2. Central Authority Of Requested State:

COMPETENT AUTHORITY FOR ENGLAND AND WALES
Senior Master of the Supreme Court of Judicature
Queen's Bench Division
ROYAL COURTS OF JUSTICE
Strand
London WC2A 2LL
England, United Kingdom

On behalf of:
THE CENTRAL AUTHORITY FOR THE UNITED KINGDOM
Her Majesty's Principal Secretary of State for Foreign Affairs
FOREIGN AND COMMONWEALTH OFFICE
King Charles Street
London SW1A 2AH, England,

UNITED KINGDOM

3. Person To Whom The Executed Request Is To Be Returned

Defendants' UK Legal Representative
David Rose
SJ Berwin LLP
10 Queen Street Place
London EC4R 1BE
England, United Kingdom

Plaintiff's UK Legal Representative
Daniel Brook
Hogan Lovells International LLP
Atlantic House
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on behalf of:

The Honorable Denise K. LaRue
United States Magistrate Judge
United States District Court for the Southern District of Indiana
Birch Bayh Federal Building and
United States Courthouse
46 East Ohio Street, Room 105
Indianapolis, IN 46204
United States of America

4. In conformity with Article 3 of the Hague Convention, the undersigned applicant has the honor to submit the following request:

5a. Requesting judicial authority:

The Honorable Denise K. LaRue
United States Magistrate Judge
United States District Court for the Southern District of Indiana
Birch Bayh Federal Building and United States Courthouse
46 East Ohio Street, Room 105
Indianapolis, IN 46204
United States of America

5b. To the competent authority of:

THE UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND

6. Names and addresses of the parties and their representatives:

a. Defendants:

Teva Parenteral Medicines, Inc.
19 Hughes
Irvine, California 92618
United States of America

APP Pharmaceuticals, LLC
Three Corporate Drive
Lake Zurich, Illinois 60047
United States of America

Pliva Hrvatska d.o.o.
Prilaz baruna Filipovica 25
10000 Zagreb, Croatia

Teva Pharmaceuticals USA, Inc.
1090 Horsham Road
North Wales, Pennsylvania 19454
United States of America

Barr Laboratories, Inc.
400 Chestnut Ridge Road
Woodcliff Lake, New Jersey 07677
United States of America

Defendants' UK Legal Representative:

David Rose
SJ Berwin LLP
10 Queen Street Place
London EC4R 1BE

England, United Kingdom

Defendants' U.S. Legal Representatives:

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b. Plaintiff:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Plaintiff's UK Legal Representative:

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Plaintiff's U.S. Legal Representatives:

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7. Nature and purpose of the proceedings and summary of the facts:

This is a civil action, filed by Plaintiff Eli Lilly and Company ("Lilly") against Defendants Teva Parenteral Medicines ("Teva Parenteral"), APP Pharmaceuticals, LLC ("APP"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Pliva Hrvatska d.o.o. ("Pliva"), and

Barr Laboratories, Inc. ("Barr") (collectively known as "Defendants") alleging patent infringement pursuant to title 35, section 271 of the United States Code.

PARTIES

Lilly is a corporation organized under the laws of the State of Indiana and has its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

Teva Parenteral is a corporation organized under the laws of the State of Delaware and has its principal place of business at 19 Hughes, Irvine, California 92618.

APP is a limited liability company organized under the laws of the State of Delaware and has its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

Teva USA is a corporation organized under the laws of the State of Delaware and has its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

Pliva Hrvatska d.o.o. is a limited liability company organized under the laws of the Republic of Croatia with its principal place of business at Prilaz baruna Filipovica 25, 10000 Zagreb, Croatia.

Barr is a corporation organized and existing under the laws of the State of Delaware and has its principal place of business at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

SUMMARY OF PLAINTIFF'S COMPLAINTS

Lilly owns New Drug Application No. 21-462 for ALIMTA® brand pemetrexed disodium for injection. ALIMTA® is approved by the U.S. Food and Drug Administration ("FDA") for the treatment of nonsquamous non-small cell lung cancer and malignant pleural mesothelioma. The physician prescribing information for ALITMA® states that patients treated with ALIMTA® should take folic acid and vitamin B_{12} with ALITMA®. *See* ALIMTA® label (Exhibit 1) at 1.

Lilly alleges that U.S. Patent No. 7,772,209 ("the '209 patent," Exhibit 2) covers the FDA approved method of using pemetrexed disodium for injection (*i.e.*, ALIMTA®) with folic acid and vitamin B_{12}. The '209 patent issued from U.S. Patent Application No. 11/776,329, which claims priority to several patent applications, the earliest of which was filed on June 30, 2000. Dr. Niyikiza is the sole named inventor on the face of the '209 patent. The '209 patent claims are directed to, *inter alia*, the administration of folic acid and vitamin B_{12} with pemetrexed.

Defendants have filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to sell pemetrexed disodium for injection, a generic version of ALIMTA®. Teva Parenteral filed ANDA Nos. 90-352 and 90-674, APP filed ANDA No. 90-384, and Pliva, Barr, and Teva USA filed ANDA No. 91-111. In its Complaint, Lilly alleges that each of the Defendants infringed the '209 patent by providing the FDA with a "Paragraph IV Certification [21 CFR 314.94(a)(12)(i)(A)(4)]," also referred to as a "PIV certification," in connection with filing of each of their respective ANDAs. Each of the PIV certifications allege that the '209 patent "is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of" each of the Defendants' ANDA products.

SUMMARY OF DEFENDANTS' ANSWERS AND DEFENSES

Defendants deny Lilly's infringement allegations and have asserted numerous defenses relating to the validity of the '209 patent, two of which are that the claims are invalid under 35 U.S.C. § 103 and 35 U.S.C. § 116. As discussed in more detail below, Dr. Calvert has documentary and testimonial information relevant to at least these two defenses.

STAGE OF THE PROCEEDINGS

Discovery is underway. The parties have produced documents and taken fact depositions. Expert depositions are ongoing.

8. Evidence to be Obtained:

WITNESS FROM WHOM EVIDENCE IS SOUGHT

Defendants seek documents and oral testimony for trial from Dr. Calvert. Dr. Calvert was involved in the 1990s and early 2000s in the preclinical and clinical development of ALIMTA®, which is in the class of drugs known as antifolates, and in the development of other antifolates also proprietary to Lilly. Dr. Calvert's involvement included the disclosure of advice and ideas to Lilly and to the named inventor of the '209 patent, Dr. Niyikiza, who at the time was an employee of Lilly, regarding the administration of folic acid and vitamin B_{12} with antifolates.[1] As explained in more detail below, Dr. Calvert is in possession of evidence and information that is relevant to Defendants' invalidity positions in this lawsuit.

This Hague request is necessitated by the refusal of Dr. Calvert to voluntarily produce documents or to voluntarily make himself available for deposition.

RELEVANCE OF THE EVIDENCE SOUGHT

Dr. Calvert has documentary and testimonial information relevant to the Defendants' defenses in this litigation.

By the 1990s, Lilly established an antifolate research program that focused on developing antifolates for treating cancer. At least three antifolate compounds were of significant interest – pemetrexed, LY309887, and lometrexol. As part of its research and development effort, Lilly

[1] The facts represented herein are Defendants' contentions. Lilly does not consent that any of these facts have been established.

worked with outside consultants in the fields of antifolates, cancer treatment, and vitamin metabolism. Dr. Calvert was one of those outside consultants.

As early as 1990, Lilly began clinical studies of the antifolate lometrexol, and as early as 1996, Lilly began clinical studies for both LY309887 and pemetrexed. As of 1996, the trial protocols for these studies did not encompass the administration of vitamin B_{12}. By 1997, Lilly and its clinical investigators observed that in their respective clinical trials, LY309887 and pemetrexed caused serious toxicities. For instance, in a Phase II pemetrexed clinical trial concerning the treatment of gastric cancer, three of the first six patients enrolled in the trial died from treatment-related toxicities, and in December 1997, Lilly suspended LY309887 clinical trials due to the occurrence of a treatment-related death.

Lilly searched for a solution to the toxicity problem associated with the use of these antifolates. In the summer and fall of 1997, through discussions and meetings with Dr. Calvert and other external consultants, Lilly observed that folic acid and vitamin B_{12} supplementation might ameliorate the toxicities caused by LY309887 and pemetrexed. For instance, in August 1997, Dr. Calvert told Lilly about the clinical manifestations of vitamin B_{12} deficiencies. *See* Exhibit 3. Throughout the search for a solution to the toxicity problem (*i.e.*, at least August to October 1997 and December 1999), Dr. Calvert communicated with and potentially influenced key Lilly decision-makers about the decision to add folic acid and vitamin B_{12} to the ALIMTA® regimen. Upon information and belief, Dr. Niyikiza did not conceive the idea of using vitamin supplementation to ameliorate the toxicities caused by LY309887 and pemetrexed until after he communicated with Dr. Calvert.

As part of his role as an outside consultant, Dr. Calvert was in contact with members of a Lilly "Core Team," comprising a group of Lilly employees responsible for the clinical

development of pemetrexed and other antifolates such as LY309887 and involved in making decisions regarding vitamin supplementation. *See* Exhibit 4. Dr. Calvert was also a member of the Antifolate Advisory Panel, which was a panel of outside consultants that Lilly consulted regarding the clinical development of pemetrexed and LY309887. *See* Exhibit 5. In this litigation, Lilly identified Dr. Calvert as an individual who "advised or consulted with Lilly during preclinical or clinical development of pemetrexed with respect to vitamin supplementation," specifically with respect to "[c]ollection of markers for vitamin deficiency and the effects of vitamin administration." *See* Exhibit 6 at 21 (Lilly's Response to Defendants' Interrogatory No. 6). Dr. Calvert also attended and presented at conferences in 1997 that were relevant to Dr. Calvert's work on antifolates and vitamin supplementation. Specifically, Dr. Calvert presented at a European Cancer Organization ("ECCO") conference in mid-1997, and was a panelist discussing pemetrexed at a satellite symposium held in conjunction with the British Association on Cancer Research on April 1, 1997.

Dr. Calvert's information regarding his role in the clinical development of these antifolates is relevant to at least two of Defendants' defenses: (1) the methods of use claimed in the '209 patent are obvious under 35 U.S.C. § 103, and (2) the '209 patent claims are invalid 35 U.S.C. § 116 because Lilly failed to name the correct inventors.

Defendants contend, among other things, that the claims of the '209 patent are invalid as obvious under 35 U.S.C. § 103, in part, because information that qualifies as prior art under 35 U.S.C. § 102(f) rendered the claims of the '209 patent obvious to a person of ordinary skill in the art in combination with other pieces of prior art.

Section 103(a) states that:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this

> title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

An obviousness analysis requires three basic factual inquiries: (1) determining the scope and content of the prior art; (2) ascertaining the difference between the claimed invention and the prior art; and (3) resolving the level of ordinary skill in the pertinent art. "Prior art" is generally defined by 35 U.S.C. § 102, and the United States Court of Appeals for the Federal Circuit has specifically confirmed that information that qualifies as prior art under § 102(f) may be combined with other forms of prior art to invalidate claims under Section 103. *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d 1396, 1401-05 (1997).

Section 102(f) states that:

> A person shall be entitled to a patent unless -
>
> *****
>
> (f) he did not himself invent the subject matter sought to be patented.

The Federal Circuit held that "a fair reading of § 103, as amended in 1984, leads to the conclusion that § 102(f) is a prior art provision for purposes of § 103." *OddzOn*, 122 F.3d at 1401. The Court explained that "subject matter derived from another not only is itself unpatentable to the party who derived it under § 102(f), but, when combined with other prior art, may make a resulting obvious invention unpatentable to that party under a combination of §§ 102(f) and 103." *OddzOn*, 122 F.3d at 1404.

In this case, Defendants contend that the claims of the '209 patent are invalid as obvious over prior art material. Defendants further contend that Dr. Calvert conceived of the idea to add

folic acid and vitamin B_{12} to the cancer treatment regimen for one of Lilly's antifolates compounds known as LY309887, and that Dr. Calvert communicated his conception to individuals at Lilly and to Dr. Niyikiza as early as August 1997. In other words, Defendants contend that Dr. Niyikiza derived the idea of adding folic acid and vitamin B_{12} supplementation to an antifolate cancer treatment regimen from Dr. Calvert. Dr. Calvert's communications to Lilly regarding folic acid and vitamin B_{12} supplementation are therefore prior art under § 102(f) and relevant to Defendants' defense that the claimed methods of use regarding the administration of folic acid and vitamin B_{12} with pemetrexed are obvious.

Defendants also contend that the claims of the '209 patent are invalid for failing to name the proper inventors under 35 U.S.C. § 116. Section 116 states, in part, that:

> When an invention is made by two or more persons jointly, they shall apply for patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

In this case, Defendants contend that numerous individuals, including Dr. Calvert, contributed to the research and development of the subject matter claimed by the '209 patent, and that it is improper for Lilly to list Dr. Niyikiza as the sole inventor. In other words, Defendants contend that Dr. Calvert contributed to the alleged conception of the methods of use claimed in the '209 patent, and for that reason, Dr. Calvert should have been listed as an inventor.

For the reasons set forth above, the District Court believes that Dr. Calvert will be able to provide evidence directly relevant to issues in dispute between the parties and without which the ends of justice could not be properly served. Defendants believe that Dr. Calvert has information relevant to the following issues that impact the validity of the '209 patent: (1) whether Dr. Calvert created § 102(f) prior art that, in combination with other art, renders the '209 patent

claims obvious, and (2) whether the '209 patent claims are invalid because Dr. Calvert was not identified as a named inventor of the '209 patent. Dr. Calvert has refused to voluntarily produce documents or to voluntarily make himself available for deposition.

DOCUMENTS SOUGHT FOR PRODUCTION

See **Appendix A**.

SUBJECT MATTER FOR ORAL EXAMINATION

See **Appendix B.**

9. Identities and addresses of persons to be examined:	Dr. Hilary Calvert Beech House, Burn Road Blaydon-on-Tyne Tyne and Wear NE21 6JR UK
10. Questions to be put to the persons to be examined or statement of the subject matter about which they are to be examined:	Please see itemized subject matter list in **Appendix B**.
11. Documents or other property to be inspected:	See **Appendix A**.
12. Any requirement that the evidence be given on oath or affirmation and any specific form to be used:	The witness should be examined under oath or affirmation, or in the alternative, should be instructed of the consequences for the giving of untruthful and false answers under the laws of England and Wales.

13. Special methods or procedures to be followed:

The District Court respectfully requests, with respect to the oral testimony being sought:

(1) That the Senior Master appoint an English Examiner for the purpose of compelling oral testimony from the witness for use at trial;

(2) That Defendants' counsel, David Rose, a solicitor with the London firm of SJ Berwin LLP, arrange for the nomination of an English barrister to act as Examiner in this matter. This Request is made pursuant to, and in conformity with, Chapter I of the Hague Evidence Convention of March 18, 1970, the Evidence (Proceedings in Other Jurisdictions) Act 1975, the

Rules of the District Court Order 70, and Rule 34, paragraphs 6 and 8 of the Civil Procedure Rules; and

(3) That the parties' representatives or their designees, a court reporter and a videographer be permitted to be present during the examination; that the representatives or designees be permitted to examine and cross-examine the witness directly; and that a court reporter and a videographer be permitted to make a verbatim record of the proceedings.

In addition, the District Court requests, with respect to the documents being sought:

(1) That such orders be entered as English law permits directing that Dr. Calvert produce specific categories of documents in electronic form or, whenever production in electronic form is impractical, make such documents available for inspection and copying by Defendants' counsel, David Rose, at a time and place to be determined by the High Court, but at least fourteen days prior to examination of Dr. Calvert. A list of the documents that are requested is set forth in attached **Appendix A**;

(2) That the Senior Master enter an order that any documents produced in response to this Request shall be authenticated in accordance with the High Court's customary practice with any fees borne by Defendants;

(3) That the Senior Master enter an order that for each document produced in response to this Request, Dr. Calvert must certify that said document is an original or a copy of Dr. Calvert's file or record;

(4) That the Senior Master enter an order that for each document produced in response to this Request, Dr. Calvert must certify whether said document is an original or copy of a file or record that was in the possession or custody of Dr. Calvert;

(5) That the documents so produced be submitted directly to Defendants' counsel, David Rose;

(6) Given the importance of the evidence to be obtained, that these Requests be given the highest consideration; and

(7) To the extent that any portion of Letter of Request cannot be granted, it is respectfully requested that the remaining parts be granted.

The information discovered in this litigation is subject to a Stipulated Protective Order ("Protective Order" attached hereto as Appendix C) designed to limit the disclosure of confidential business information. The Protective Order provides that either party or a non-party may designate documents, things or information as Confidential. **Appendix C**, at ¶¶ 3, 22. Such

designation under the Protective Order protects the producing entities from unauthorized use and/or disclosure of trade secrets and other proprietary information. Specifically, material designated Confidential may not be disclosed to any person except, *inter alia*, counsel for all parties in the Action, certain representatives of the parties in the Action, the Court and Court personnel in the Action; and other third parties, including experts, consultants, accountants, and fact witnesses, who are bound by the terms of the Protective Order. *Id.* at ¶ 6. Additionally, information designated as "Confidential" must not be used "for any purposes other than in connection with this action … including without limitation for … other competitive purpose[s]." *Id.* at ¶ 5.1. If any party has objections to the designation of any document/information as "Confidential," it may request in writing the removal of such designation. Until the Court rules on whether the materials in question are properly designated, all documents and information remain so designated. *Id.* at ¶ 5.1, 16. Thus, any confidential information provided by Dr. Calvert can be protected from disclosure to the public and can be protected from disclosure to non-attorney employees of the parties to the litigation. The District Court additionally requests that the confidentiality of any evidence produced as a result of this Request be maintained pursuant to the laws of the United Kingdom and the Protective Order entered by the District Court (attached hereto as **Appendix C**).

In any event, within 90 days after the conclusion of this action, including all appeals, all designated material and all copies thereof must be returned to the designating person, or counsel of record may certify in writing that such material has been destroyed, except that counsel for each party may archive copies of all filings, court papers, correspondence, deposition and trial transcripts, deposition and trial exhibits, expert reports, written discovery responses, and attorney work product. *Id.* at ¶ 23.

14. Request for notification of the times and place for the execution of the Request and identity of the person to be notified:	It is requested that testimony be taken at such place, date or time as ordered by the Senior Master and/or as otherwise scheduled by the representatives of the Defendant and/or as otherwise agreed to by the witness and the respective representatives of the Parties. ***Notice thereof should be made to Defendants' UK designee:*** David Rose SJ Berwin LLP 10 Queen Street Place London EC4R 1BE England, United Kingdom ***Plaintiff's UK Legal Representative:*** Daniel Brook Hogan Lovells International LLP Atlantic House Holborn Viaduct London EC1A 2FG Telephone: +44 20 7296 2000 Facsimile: +44 20 7296 2001 daniel.brook@hoganlovells.com
15. Request for attendance or participation of judicial personnel of the requesting authority at the execution of the Letter of Request:	None.

16. Specification of privilege or duty to refuse to give evidence under the laws of the State of origin:

Under the laws of the United States, a party has a privilege to refuse to give evidence if the evidence discloses a confidential communication between that party and an attorney for that party that was made for the purpose of obtaining legal advice.

Parties also enjoy limited privileges on other grounds not relevant here such as communications between physician and patient, psychotherapist and patient, husband and wife, or clergy and penitent.

US law also recognizes a privilege against criminal self-incrimination.

Outside the strict area of privilege, certain limited immunities are available that may place restrictions on the giving of evidence, such as the limited protection of documents created as the work product of attorneys during or in anticipation of litigation.

17. The fees and costs incurred which are reimbursable under the second paragraph of Article 14 or under Article 26 of the Convention will be borne by:

Defendants Teva Parenteral Medicines, APP Pharmaceuticals, LLC, Teva Pharmaceuticals USA, Inc., Pliva Hrvatska d.o.o., and Barr Laboratories, Inc.

c/o Defendants' legal representative in the U.S.:

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This Court also assures your authority that it will reciprocate with similar assistance in like cases and extends to the Judicial Authorities in the United Kingdom the assurances of its highest consideration.

Date of request 05/14/2013

Signature and Seal of the Requesting Authority:

Denise K. LaRue
United States Magistrate Judge
Southern District of Indiana